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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

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WEITSCHIES ET AL.

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Group Art Unit: 1641

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Serial No.: 08/894,767

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Examiner: P. DO

MAR - 6 2003

Filed: FEBRUARY 23, 1998

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OFFICE OF PETITIONS

For: PROCESS AND COMPOUNDS FOR DETECTION OF ANALYTES USING  
REMANENCE MEASUREMENT, AND USE THEREOF

PETITION OF RESTRICTION REQUIREMENT UNDER 37 C.F.R. §1.181

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This is a petition requesting the Commissioner, through the Honorable group director, to withdraw the requirement for restriction mailed July 5, 2000. This requirement was made final in the Office Action mailed August 4, 2000, and has been continuously traversed thereafter.

Statement of Facts

The requirement for restriction mailed July 5, 2000, divided the invention into four groups:

Group I, claims 1, 2, 4, 5, 8-25, 39, drawn to a method of qualitative and/or quantitative detection of analytes in liquid/solid phases using ferromagnetic or ferromagnetic substances as labels.

Group II, claims 3, 6, 7, drawn to a method of quantitative and/or qualitative detection of analytes in immunoassays or other binding assays using magnetic field sensors and external

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magnetic field.

Group III, claims 26, 32, 36-38, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body.

Group IV, claims 27-31, 35, drawn to a method for detection of ferromagnetic substances that are introduced into a human body or applied to a human body using external magnetic field and magnetic field sensors.

In response to the requirement for restriction, on August 4, 2000, Applicants elected Group I, claims 1, 2, 4, 5, 8-25 and 39 drawn to a method of qualitative and/or quantitative detection of analytes in liquid or solid phases, using ferromagnetic or ferromagnetic substances as labels. Claims 1-3, 5-18, 22-32 and 35-42 are currently within the elected group, claims 3, 6, 7, 26-32 and 35-38 have been withdrawn.

#### Summary of Argument in Support of Withdrawal of Restriction Requirement

The claims on Groups I and II employ ferromagnetic or ferrimagnetic substances to detect analytes and those in Groups III and IV use ferrimagnetic or ferromagnetic substances to detect magnetically labelled structure-specific substances in a human. The claims of Groups II and IV further recite that external magnetic fields are employed. It is thus respectfully submitted that all four groups employ the "same or corresponding special technical feature", that is, the use of ferrimagnetic or ferromagnetic substances as labels to detect substances either *in vitro* or *in vivo*. In all four groups of claims the technical features of the invention are essentially the same, that is, materials labeled with magnetic substances are detected through the use of typical magnetization detection techniques. It does not matter whether the sample measured is a human, or an analyte in vitro, nor does it matter whether or not an external magnetic field is used (in fact, the Office Action does not suggest what process other than an external magnetic field could be employed). Thus, the "special patentable feature" is not the use of external sensors or the use of detection techniques in human bodies; rather the same procedure and "special patentable feature" is being applied regardless of on what or where the detection techniques are being used. Thus, it is submitted that, under 37 C.F.R. §1.475, the groups of invention set forth in the Requirement for Restriction do not contain different special

patentable features and, therefore, that the Restriction Requirement should be withdrawn.

#### Detailed Discussion

The present case is a PCT National Phase application, and thus subject to the unity of invention requirements codified in 37 C.F.R. §1.475. Under this section of the rules, it is submitted that the groups of claims herein should be maintained together as the same procedure and same special patentable feature are applied *regardless* of how the detection techniques are employed in the various groups of claims. The inventive concept, for example, as set forth in claim 1, relates to the use of magnetically-coupled structure specific substances to measure analytes in a liquid or solid phase. Selection of particular bound magnetic markers is wholly conventional in view of the guidance given in the specification, and does not require undue experimentation. The inventive concept does not vary with the particular material or analyte bound, but all bound ligands are used in the invention in a similar manner. Thus, the inventive concept does not change regardless of any material employed therein. The materials are, in fact, especially adapted for use in the process claimed, and thus are part of a single inventive concept. While the Office Action of October 25, 2000 disputes this argument by doubting patentability of the claims based on this special technical feature, (see page 2 thereof) it is submitted that this reflects a misunderstanding of the PCT unity of invention rules, in which patentability is not a prerequisite for unity of invention. The fact that the claims all recite the same special technical feature is sufficient to maintain the groups of claims together.

In the final rejection of December 3, 2002, this argument appears to shift somewhat, where it is now maintained that "the special technical feature" is the use of an external magnetic field and magnetic field sensors. This is, however, a gross mischaracterization of the special technical feature possessed by the four groups as defined in the restriction requirement. Indeed, at page 5 of the final rejection, in a discussion of why the elected claims are free of prior art and thus patentable, the Office Action admits that the "prior arts [sic] do not teach a method of qualitative and/or quantitative detection of analytes in a liquid and/or solid phase homogeneous assay, comprising determining the remanence magnetization in said homogeneous assay after addition to a sample of a stable or quasi-stable ferromagnetic or

ferromagnetic [sic, ferrimagnetic] substances." Indeed, as discussed in the present specification, and urged in arguments in support of patentability, the special technical feature which defines patentability over the prior art herein is the ability of the system claimed to enable determining the presence of the analyte, without the requirement for separation of unbound magnetic markers. While some of the claims explicitly recite the use of an external magnetic field, and other claims do not, this is an impermissible basis (the use of an external magnetic field) upon which to base the restriction requirement. The use of an external magnetic field is wholly conventional. Moreover, the invention cannot be practiced without the use of a magnetic field, inasmuch as such is needed to produce and assess remanence magnetization.

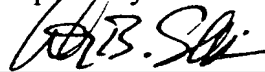
#### Conclusion

It is therefore respectfully submitted that all the claims in the present application require the same special technical feature, that is, the use of remanence magnetization to determine the presence of the analyte without separation of unbound markers. Moreover, it is submitted that the "special technical feature" identified in the Office Action cannot be a permissible basis for restriction. Withdrawal of the restriction requirement is therefore proper, and is respectfully requested that the same be directed.

Attached please find a check in the amount of \$130.00, the Petition fee required under 37 CFR 1.17(h).

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Harry B. Shubin, 32,004  
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

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